

## **REMARKS**

Claims 1-4 and 6-11 are pending in the present application. Claim 5 has been cancelled herein. New claims 7-11 have been added. Applicant submits that no new matter has been added by way of the above amendments.

### **Information Disclosure Statement**

The Examiner states that Applicant has not supplied any translations of JP-4-226925-A and JP-2000-510006-A and JP-2001-122791-A. However, Applicant submitted USP 5,158,975 as the English equivalent of JP-4-226915-A and WO97/40755 as the English equivalent of JP-2000-510006-A in the Information Disclosure Statement filed on December 19, 2005. Moreover, the relevance of these documents (i.e., JP-4-226915-A and JP-200-51006-A) was discussed in the Written Opinion of the PCT, which Applicant submitted on June 8, 2006. With regard to JP-2001-122791, Applicant has provided a translation of the relevant portion of the document. Accordingly, it is submitted that Applicant has fully complied with the rules. Accordingly, Applicant respectfully requests that the Examiner indicate the noted references as having been considered.

### **Rejection under §112, first paragraph**

Claims 1-6 stand rejected as being broader than enabled.

In response to the outstanding rejection, the recitations of "prevention" and "prophylactic" have been deleted from the claims. Thus, the scope of each of the pending claims is limited to reducing incidence of varicose veins, treating varicose veins, alleviating symptoms of varicose veins or a therapeutic agent for varicose veins. Withdrawal of the outstanding rejection is respectfully requested.

**Rejection under §112, second paragraph**

Claim 5 which recites "Use of eicosapentaenoic acid in the manufacture" is cancelled herein. Claim 6, depends from claim 3 which recites a therapeutic agent and defines the administration route and the dose amount. Accordingly, withdrawal of the outstanding rejection is respectfully requested.

**Rejection under §102**

Claims 1-3 and 5 stand rejected under §102(b) as being anticipated by Yazawa et al. (EP 404300). Applicant respectfully traverses.

The Examiner alleges that Yazawa et al. discloses EPA-containing phospholipids composition, the method of making the same and the use of the same in pharmaceuticals. However, Applicant respectfully disagrees.

Yazawa et al. does not disclose anything about varicose veins of lower extremities. In addition, in order to clarify the scope of the present claims, claims 1 and 3 are amended to clearly recite that the composition (claim 1) and therapeutic agent (claim 3) of the present invention do not include phospholipids. Additionally, claim 2 is dependent on claim 1 and claim 5 is cancelled. Accordingly, Applicant requests reconsideration and withdrawal of the outstanding rejection.

Claims 1-3 and 6 stand rejected under §102(b) as being anticipated by Kiliaan et al. (WO 01/84961). Applicant respectfully traverses.

The Examiner alleges that Kiliaan et al. discloses the use of EPA for vascular disorders and further for varicose veins. However, Applicant respectfully disagrees.

Kiliaan et al. describes that the mixture of

- a) polyunsaturated fatty acids,
- b) phospholipids and

- c) compounds, which are a factor in methionine metabolism can prevent and treat vascular disorders, and further describes EPA as an example of polyunsaturated fatty acids as well as varicose veins as an example of vascular disorders.

However, Kiliaan et al. and the present invention are different in that Kiliaan et al. describes the mixture of three fractions while the present invention is the composition or therapeutic agent containing EPA as the effective component. In order to clarify this difference, the rejected claims are amended to clearly define that the present invention does not include the fractions of b) phospholipids and c) compounds which are a factor in methonine metabolism of Kiliaan et al.

Moreover, Kiliaan et al. provides no particular data demonstrating that the above mixture can prevent and treat vascular disorders. Nor does Kiliaan include data to show the effectiveness in preventing and treating varicose veins. On the other hand, the present invention is distinctive in having particularly presented that the therapeutic agent containing EPA as the effective component has effects in treating varicose veins of human lower extremities (See the Examples of the present application). Accordingly, Applicant requests reconsideration and withdrawal of the outstanding rejection.

Claims 1-4 and 6 stand rejected under §102(b) as being anticipated by Bruzesse (US 5776978). Applicant respectfully traverses.

The Examiner alleges that Bruzesse discloses the use of EPA for cardiovascular conditions and atherosclerosis, while the Mayo Clinic sheets show that the cardiovascular conditions encompass varicose veins. Applicant respectfully disagrees.

Bruzesse describes that the combination of polyunsaturated fatty acids and 10-40% by weight of antioxidant vitamins is useful for preventing and treating cardiovascular diseases and the like, and further describes EPA and their esters as examples of the polyunsaturated fatty

acids. However, Bruzzesse and the present invention are different in that Bruzzesse describes the synergistic effect of the above combination while the present invention is the composition or therapeutic agent containing EPA as the effective component. In order to clarify this difference, the rejected claims are amended to clearly define that the present invention does not include 10-40% by weight of antioxidant vitamins, which is the requirement in Bruzzesse.

In addition, Bruzzesse discloses that the above combination synergistically suppresses the oxidation of LDL, however, it does not show any particular data regarding that the suppression is effective for treating varicose veins. On the other hand, the present invention is distinctive in having particularly presented that the therapeutic agent containing EPA as the effective component has effects in treating varicose veins of human lower extremities (Examples of the present application). Accordingly, Applicant requests reconsideration and withdrawal of the outstanding rejection.

In view of the foregoing, Applicant believes the pending application is in condition for allowance. A Notice of Allowance is earnestly solicited.

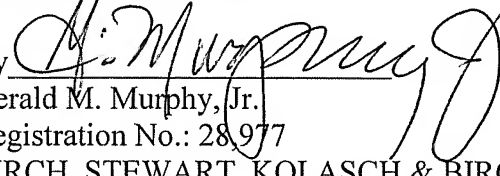
#### Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole, Reg. No. 60,154 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By 

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